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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,030	03/09/2000	James A Thomson	96-0296-96544	4331

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QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/01/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/522,030

Applicant(s)

THOMSON, JAMES A

Examiner

Joseph Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1632

DETAILED ACTION

This application is an original application filed March 9, 2000.

Applicant's amendment filed April 9, 2002, paper number 8, has been received and entered. claims 15 and 16 have been canceled. Claim 1 and 14 have been amended. Claim 17 has been added. Claims 1-14 and 17 are pending and currently under examination.

Specification

The disclosure is objected to because of the following informalities:

As noted in the previous office action, the use of the trademark KNOCKOUT SR has been noted in this application (page 6; line 22). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

Art Unit: 1632

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of culturing a primate and human pluripotent embryonic stem cell and deriving cells and cell lines therefrom, does not reasonably provide enablement for primate and human embryonic cells is withdrawn.

Applicant notes that the embryonic stem cells taught in the present disclosure are clearly pluripotent, and may be in fact totipotent. It is noted that Applicant is unaware of evidence to demonstrate that the embryonic stem cells are totipotent, and that the tests to demonstrate that embryonic stem cells are totipotent are not ethically permitted in the United States. Further, it is pointed out that the art recognizes a more encompassing use of the terminology "stem cell", and that reciting pluripotent would unduly limit the instant inventor from the full scope of their invention. See Applicant's amendment, pages 4-5. Applicant's arguments have been fully considered and found persuasive.

Specifically, the instant invention is based on experimentation and conditions developed on stem cells which are clearly known and recognized in the art. Based on the evidence of record, Examiner can find no specific reason why the conditions used for the stem cells instantly disclosed would not be suitable for any stem cell, either pluripotent or totipotent. Further, if the stem cells disclosed are shown at a later date to be totipotent, lacking any specific evidence of record at the time of filing, Examiner agrees that recitation of "pluripotent" would have been

Art Unit: 1632

unduly limiting. Therefore, in light of Applicants' arguments and in view of the evidence of record, the rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Specifically, claim amendments to claim 1 and cancellation of 15 and 16 have obviated the specific rejections over these claims.

With respect to the recitation of "essentially free of", Applicants argue that this terminology is recognized language, and in the instant case is used to avoid situations where minor contaminants may be present. See Applicants amendment, middle of page 5.

Though a specific definition of "essentially free of" is not set forth in the present specification, Examiner agrees with Applicant's arguments that in light of the teaching of the specification of "serum free conditions" and the general use and understanding in the art of "essentially free of" representing conditions which are serum free but may have minor contaminants from other sources, the pending claims are definite wherein the metes and bounds would be fairly defined and recognized by one of skill in the art.

Art Unit: 1632

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Cancellation of claims 15 and 16 have obviated the basis of each of the rejections made under 35 USC 102.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1632

Claims 1-14 stand rejected and new claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* ('372), Hogan *et al.* (926) and Goldsborough *et al.* (FOCUS 20(1):8-12, 1998).

Applicant argues that while the combination of the references provide necessary teachings, the motivation to combine the references for use in primate and human cells would not be obvious, nor that the methods if combined would actually work for cultured human and primate cells. See Applicant's amendment, page 6. Applicant's arguments have been fully considered, but not found persuasive.

It is noted, that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988). In the instant case, Examiner would agree that the art teaches that the specific methods used to isolate embryonic stem cells from different species has demonstrated unique requirements for each species. However, once the cells are isolated, the means to culture said embryonic cells are very similar and pliant to various conditions, using feeder cells and growth factors from different species. In the instant case, the Knockout SR is a serum replacement and while the media itself is unique, it does not provide a radical departure from what is required for culturing cells, and in fact is provided to make culturing more uniform and

Art Unit: 1632

less reliant on the variability of different serum lots. Note that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). In the instant case, the greatest difference between the conditions used for culturing mouse and human embryonic stem cells is the requirement for LIF. Goldsborough *et al.* provide clear guidance for the use of LIF in the culture media, and provide further evidence that LIF may not be necessary when using the fully defined serum replacement. Additionally, besides teaching the advantages of a fully defined serum supplement, Goldsborough *et al.* provide evidence that the serum replacement may be better than serum alone in maintaining undifferentiated embryonic cell colonies. In view of the teachings of the art as a whole, the cited references provide a clear motivation and a reasonable expectation of success to substitute the serum replacement taught by Goldsborough *et al.* for the serum normally used in culturing embryonic stem cells.

Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1632

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.



Joseph T. Woitach

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/630